REMARKS

Reconsideration of this application is respectfully requested.

STATUS OF THE CLAIMS

Following entry of this Amendment, claims 13-30 will be pending. Claims 13-18 have been amended. Claim 12 is cancelled. Claims 24-30 are added.

Support for the new and amended claims is as follows:

Claim 16: page 5, lines 21-22.

Claim 17: page 6, lines 2-6.

Claim 18: page 4, line 1.

Claims 24-30: page 3, line 29-30; page 3, lines 34-35; page 4, lines 1-2; page 6, lines 25-28 and 32-33; page 7, lines 5-6 and 23-27; and p. 18, lines 1-2.

No extra claims fees are believed owed as a result of the added claims, but the Commissioner is authorized to charge the above-mentioned deposit account the required amount in the event that is incorrect.

REJECTION UNDER 35 U.S.C. §102(b)

Claims 12, 13, 16, and 17 stand rejected under 35 U.S.C. §102(b) as being anticipated by Sato *et al.* In view of the cancellation of claim 12 and the amendments to claims 13, 16, and 17 the presently pending claims are submitted to not be anticipated by the cited prior art, as discussed below. Reconsideration of the rejection is respectfully requested.

According to the Examiner, Sato *et al.* teaches an antigenic composition comprising a culture filtrate antigen of *Erysipelothrix rhusiopathiae* culture (*i.e.*, fluid fraction) that is mixed with an aluminum phosphate gel. The position of the Examiner is that all the structural elements required to be present in the claimed antigen composition are taught by Sato *et al.* The Examiner further states that because the prior art aluminum phosphate gel is structurally the same as the aluminum phosphate gel in the instantly claimed antigen composition, it is expected to have the intrinsic or inherent stabilizing function.

In response thereto, Applicants have cancelled claim 12 and amended claim 13 to delete the term "aluminum phosphate." Applicants have amended claim 17 to include a stabilizing agent as part of the vaccine composition and added claim 29 to recite that the composition is stable for at least one year at 2° C to 8° C and provides immunity to weaned pigs for six months. Sato does not teach the vaccine composition of claim 17, as aluminum phosphate is described by

Sato *et al.* only to be an adjuvant and is not combined with a stabilizing agent. Nor does the Sato reference teach that any antigen composition that is stabilized for at least one year at 2° to 8° C and which provides immunity to weaned pigs for six months.

In view of these amendments, applicants request that the rejection of claims 13, 16, and 17 under 35 U.S.C. §102(b) as being anticipated by Sato *et al.* be withdrawn.

REJECTION UNDER 35 U.S.C. §102(b)

Claims 12 and 14-16 stand rejected under 35 U.S.C. §102(b) as being anticipated by Sawada *et al.* In view of the cancellation of claim 12 and the amendments to claims 14-16, the presently pending claims are submitted to not be anticipated by the cited prior art. Reconsideration of the rejection is respectfully requested.

According to the Examiner, Sawada *et al.* teaches an antigenic composition comprising a supernatant fluid (*i.e.* fluid fraction) from an *Erysipelothrix rhusiopathiae* culture which was inactivated with formalin and concentrated to 10% of its initial volume. The position of the Examiner is that all the structural elements required to be present in the claimed antigen composition are taught by Sawada *et al.* The Examiner further states that because the prior art formalin is structurally the same as the formalin in the instantly claimed antigen composition, it is expected to have the intrinsic or inherent stabilizing function.

In response thereto, Applicants have cancelled claim 12. Applicants have also amended claim 13 and claims 14-16 to be dependent on claim 13. Applicants have also added claim 29 to recite that the composition is stable for at least one year at 2° C to 8° C and provides immunity to weaned pigs for six months. Sawada does not teach addition of an adjuvant to the formalin and *E. rhusiopathiae* antigen. Nor does it teach that an antigen composition that is stabilized for at least one year at 2° to 8° C or provides immunity to weaned pigs for six months.

In view of these distinctions in the claims as amended, applicants request that the rejection of claims 14-16 under 35 U.S.C. §102(b) as being anticipated by Sawada *et al.* be withdrawn.

REJECTION UNDER 35 U.S.C. §103

Claims 12 and 16-18 stand rejected under 35 U.S.C. §103(a) as obvious over Dayalu *et al.* in view of Sato *et al.*, Wood *et al.*, and Eckhardt *et al.* In view of the cancellation of claim 12 and the amendments to claims 16-18, the presently pending claims are submitted to not be obvious over the cited prior art.

Applicants have amended claim 17 to include a stabilizing agent as part of the claimed vaccine composition and added dependent claim 29 to recite that the composition is stable for at least one year at 2° C to 8° C and provides immunity to weaned pigs for six months. Reconsideration of the rejection is respectfully requested.

The Examiner states that Dayalu *et al.* discloses a vaccine composition comprising an *E. rhusiopathiae* antigen extract. The vaccine composition comprises merthiolate as a preservative and a conventional adjuvant with Tween 80 as an amphiphilic surfactant. The Office Action states that the Wood *et al.* reference teaches that most of the immunizing antigen is found in the culture filtrate of *E. rhusiopathiae*. The Examiner states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the *E. rhusiopathiae* antigen extract in Dayalu's vaccine composition with Sato's culture filtrate antigen of *E. rhusiopathiae* culture to produce the vaccine composition of the instant invention with a reasonable expectation of success.

The presently claimed vaccine composition exhibits both increased stability and protection against *E. rhusiopathiae* infection over an extended period of time. The cited references provide no suggestion of these unexpected results. One of ordinary skill in the art would need to select from the many adjuvants and stabilizers described by the Sato *et al.* reference, without any teaching as to which would accomplish the surprising stabilizing result recited in the present claims as amended.

Applicants submit that there is no suggestion of a combination of *E. rhusiopathiae* fluid fraction with a stabilizing agent and adjuvant that provides a stable composition for at least one year at 2° C to 8° C and which provides immunity to weaned pigs for six months.

In view of the above, Applicants assert that there is no suggestion in the prior art references themselves to combine the teachings of those references, nor is there any motivation to do so with a reasonable expectation of success.

Applicants therefore request that the rejection of claims 16-18 under 35 U.S.C. §103 as being obvious over Dayalu *et al.* be withdrawn.

CONCLUSION

Applicant submits that this application is now in condition for allowance. Issuance of a notice to that effect is earnestly solicited.

Respectfully submitted,

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VERSION OF CLAIMS SHOWING CHANGES
DO NOT ENTER

Cancel claim 12.

Amend claims 13-18 as follows:

13. (Amended) [The] An antigen composition [of Claim 1], comprising an *E. rhusiopathiae* culture fluid fraction and a stabilizing agent, wherein [said] the stabilizing agent is a metal hydroxide, a metal phosphate, an aluminum hydroxide gel, [an aluminum phosphate gel], a calcium phosphate gel, a zinc hydroxide/calcium hydroxide gel or an alum.

14. (Amended) The antigen composition of Claim [1] 13, wherein [said] the *E. rhusiopathiae* culture is inactivated.

15. (Amended) The antigen composition of Claim [3] 13, wherein [said] the *E. rhusiopathiae* culture is inactivated with formalin or with beta propiolactone.

16. (Amended) The antigen composition of Claim [1] 13, wherein [said] the fluid fraction is concentrated [by about 3 fold to about 30 fold] 6 to 20X.

17. (Amended) A vaccine composition comprising [an antigen composition of Claim 1 and an adjuvant composition]

(1) an antigen composition; and,

(2) an adjuvant composition,

wherein the antigen composition comprises an *E. rhusiopathiae* culture fluid fraction and a stabilizing agent, wherein the stabilizing agent is a metal hydroxide, a metal phosphate, an aluminum hydroxide gel, a calcium phosphate gel, a zinc hydroxide/calcium hydroxide gel or an alum.

18. (Amended) A vaccine composition according to Claim [6] 17 wherein the adjuvant composition comprises from about 0.25% to about 12.5% v/v of a lecithin, from about 1% to about 23% v/v of an oil and from about 1.5% to about 8% v/v of an amphiphilic surfactant in said vaccine composition.

Kindly add the following claims:

24. The antigen composition of Claim 13, wherein said stabilizing agent is aluminum hydroxide.

25. The antigen composition of Claim 13, wherein said stabilizing agent, aluminum hydroxide is added to the concentrated composition to a final concentration of 30% v/v.

26. The vaccine composition of Claim 17, wherein said stabilizing agent is aluminum hydroxide.

27. The vaccine composition of Claim 17, wherein said stabilizing agent, aluminum hydroxide, is added to the concentrated composition to a final concentration of 30% v/v.

28. The vaccine composition of Claim 17, wherein said adjuvant composition comprises about 2% v/v lecithin, about 18% v/v mineral oil, and about 5.6% v/v Tween 80 and about 2.4% v/v Span 80 with the remaining volume being a saline solution.

29. The vaccine composition of Claim 17, wherein said composition is stable at 2°C to 8°C for at least one year and provides immunity to weaned pigs for six months.

30. A vaccine composition comprising:

(1) an antigen composition; and,

(2) an adjuvant composition,

wherein the antigen composition comprises an *E. rhusiopathiae* culture fluid fraction and a stabilizing agent wherein the stabilizing agent is aluminum hydroxide gel; and,

wherein the adjuvant composition comprises about 2% v/v lecithin, about 18% v/v mineral oil, and about 5.6% v/v Tween 80 and about 2.4% v/v Span 80 with the remaining volume being a saline solution.